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Institute of Clinical and Translational Sciences

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# Institute of Clinical and Translational Sciences News, Vol.1, Issue 2

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# ICTS NEWS

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## Special points of interest:

- NIH Expands CTSA Consortium to 38 Sites
- Brain, Behavior, Performance Unit
- ICTS External Advisory Board Convenes
- Have you met Dr. Ana Iltis?

Embedded weblinks are designated by blue text and can be accessed in the online version of ICTS News on our website at [icts.wustl.edu](http://icts.wustl.edu).

## RESEARCH DESIGN AND BIOSTATISTICS GROUP (RDBG)

The Research Design and Biostatistics Group (RDBG) assists ICTS members with research design, data collection, study management and data analysis. J. Philip Miller, Professor of Biostatistics at Washington University is Director of this ICTS Core.

The RDBG consists of a group of eminent biostatisticians with expertise in clinical trial design, analysis and interpretation of data. The advice from one of these experts, Mae Gordon, PhD, Professor of Biostatistics and Ophthalmology and Visual Sciences, is "Come to the RDBG early and often!"

Early collaboration with the RDBG can help ICTS investigators, whether basic or clinical, to increase the rigor and the efficiency of their research studies. RDBG input can help new investigators as well as experienced investigators to write research proposals that are more competitive under review. Services include study design, forms, data management systems,

statistical analyses as well as the development of new outcome measures and new statistical approaches.

The consultants emphasize that the design of the study affects everything else, including the ability to secure grant funding and publications. Although researchers often focus on sample size, the study design consists of much more. By considering such factors as methods of reducing measurement variability, index of agreement and the timing of the measurements in the testing cycle, the optimal sample size can be affected.

How does the biostatistician become informed about the nuances of a research question? The first step is to identify the research question and key publications published in that area. "We expect investigators to publish manuscripts as good as the best manuscripts already published," said Dr. Gordon. By understanding the limitations of published studies, the

members of the RDBG are able to understand the current state of the knowledge in the area of research and provide advice accordingly.

How does a researcher contact RDBG for assistance? Call for an appointment, walk in during office hours, send an [email](mailto:rt-rdbg@rt.biostat.wustl.edu) or fill out the form accessed from the [ICTS web-site](http://icts.wustl.edu). Many of the RDBG consultation services are provided to ICTS members at no cost since the services are fully subsidized by the NIH CTSA grant. Fees may be applied for ongoing biostatistical support on funded protocols.

Phone: 314-362-2271

Email: [rt-rdbg@rt.biostat.wustl.edu](mailto:rt-rdbg@rt.biostat.wustl.edu)

Clinic Location:

Barnard 3349

3<sup>rd</sup> floor, Barnard Hospital

Clinic Hours:

Tue: 9 am – Noon

Thu: 1 – 4 pm

Website:

<http://icts.wustl.edu/cores/rdbg.aspx>

## MESSAGE FROM THE DIRECTOR

DR. KENNETH S. POLONSKY

On May 29<sup>th</sup> the NIH announced the addition of 14 academic health centers to the CTSA program, bringing the total to 38 institutions. NIH and NCRR expect to eventually support 60 institutions in this consortium of medical research institutions promoting clinical and translational re-

search. (News release at <http://www.ctsaweb.org/>.) Representatives from each CTSA participate in workgroups and committees to develop relationships and build the infrastructure necessary to meet the challenges that accompany increased collaboration across institu-

tions. As a result, membership in the ICTS provides access not only to the umbrella of cores and services in the WU ICTS, but also the evolving infrastructure of the wider CTSA community. See the ICTS website ([icts.wustl.edu](http://icts.wustl.edu)) for instructions on how to join.

## PROGRAM HIGHLIGHT: BRAIN, BEHAVIOR, PERFORMANCE UNIT (BBPU)

The Brain, Behavior and Performance Unit (BBPU), a core with specialized infrastructure and expertise in the performance of clinical research studies of the nervous system, is directed by Joel S. Perlmutter, MD, Head of the Movement Disorders Section, Department of Neurology. Faculty across the disciplines of psychiatry, neurology, occupational therapy and physical therapy contribute their expertise within the BBPU.

Services are provided at different levels of interaction; a) collaboration on research plan development, study design and data management;

b) consultation on specifics of testing and data analysis, and c) testing only, for researchers with specific requests. Specialized testing for muscle strength and function, quantified measures of movement, performance-based measures of daily living activities and quality-of-life measures are supported as well as key infrastructure support, including common database collection, retrieval and transfer of all research information.

Johanna Hartlein, RN, APN is the administrative coordinator of all studies and services provided by the BBPU. Located on the ground floor of the McMillan Building, the

newly renovated space includes areas such as examination rooms, a procedure room, physiological and psychometric testing rooms, and kinematics and muscle strength testing rooms as well as working space for faculty, staff, research fellows, students and resident trainees. A state-of-the-art exercise and movement measurements laboratory are also in the planning stage.

For more information, contact Dr. Perlmutter at [perlmutter@wustl.edu](mailto:perlmutter@wustl.edu) or 314-362-6026 or Johanna Hartlein at [johanna@npg.wustl.edu](mailto:johanna@npg.wustl.edu) or 314-362-0420.

*"The Bear Cub Fund is important because it helps scientists demonstrate that their projects have commercial value."*

Samuel L. Stanley, MD

Vice Chancellor for Research  
Washington University

## ICTS MEMBERSHIP, HOW AND WHY

Nearly 300 people have become ICTS members, gaining access to the ICTS Cores and services. Benefits also include increased exposure to national CTSA opportunities and collaborative relationships, ability to participate in ICTS research training programs and ability to apply for ICTS pilot and novel methodologies funding.

ICTS members must be from an [ICTS partner institution](#) and also fall into one of the following categories:

- Investigators who conduct or participate in clinical and/or translational research.
- Community and Industrial Partners that are collaborating with ICTS investigators.
- Students and trainees who wish to participate in ICTS

educational or training programs.

Obligations of membership include standard reporting requirements and funding acknowledgement expectations and are outlined on the ICTS website.

To register, fill out the simple [registration form](#) on the ICTS website ([icts.wustl.edu](http://icts.wustl.edu)).

## BEAR CUB FUNDS AWARDED

BY CAROLINE ARBANAS

Washington University has awarded 4 Bear Cub Fund grants totaling \$150,000 to support research projects that could be attractive for licensing by commercial entities or serve as the foundation for a startup company.

The grants were awarded to William A. Frazier, PhD, Professor of Biochemistry & Molecular Biophysics; Gerald Linette, MD, PhD, Assistant Professor of Medicine; Daniel

W. Moran, PhD, Assistant Professor of Biomedical Engineering; and Burton Wice, PhD, Research Assistant Professor of Medicine, and Kenneth Polonsky, MD, the Adolphus Busch Professor of Medicine and Head of the Department of Medicine.

The Bear Cub Fund is administered through the University's Office of Technology Management. Supported by endowment income and capi-

tal from private sources, awards can be given only to WU employees, but research supporting collaborations between ICTS partners are eligible.

The deadline for the next round of Bear Cub applications is Oct. 31. More information about the Bear Cub Fund can be found at [otm.wustl.edu/bearcubfund](http://otm.wustl.edu/bearcubfund). For more details about the current awards, go to <http://record.wustl.edu/news/page/normal/11863.html>.

## ICTS EXTERNAL ADVISORY BOARD: ADVICE & REVIEW FROM OUR PEERS

The ICTS External Advisory Board (EAB) convened for the first time on February 29, 2008. Chaired by Robert S. Sherwin, MD, Director of the Yale Center for Clinical Investigation, the Board is comprised of members from respected institutions around the country (see [membership list](#) on the ICTS website). Among the members are representatives from some of the 2006 CTSA funded institutions: Mayo Clinic, University of Pennsylvania, University of Pittsburgh and Yale University.

The role of the External Advisory Board is to provide

advice and direction to the ICTS Director and governance committees. Board members will visit WU on an annual basis and have access to documents, facilities and personnel to gain critical insights into ICTS programs in order to evaluate strengths and opportunities for growth.

The February full-day meeting agenda allowed detailed discussion of four ICTS programs; Center for Applied Research Sciences (CARS formerly GCRC), Center for Biomedical Informatics (CBMI), Clinical Research Training Center (CRTC), and the Center for Community Based Research (CCBR).

The Board documented specific comments and suggestions for each program in their report which was included in the annual progress report as required by NIH.

General consensus was expressed from the Board that the ICTS is making marked progress in its first year and is on the right path to accomplish its long-term goals.

The Board will meet once annually, with the next meeting tentatively scheduled for January 25-26, 2009.

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## WHAT HAPPENED LAST MONTH?

### HIGHLIGHTS FROM JUNE

- June 12: Center for Clinical Research Ethics (CCRE) director James DuBois, PhD hosted a conference funded by the NIH, "Informed Consent: Assessing Decisional Capacity and Enhancing Understanding." The event was attended by over 60 people from the St. Louis area. Keynote speakers included Drs. Paul Appelbaum, William Carpenter, and Charles Lidz, all leading researchers in psychiatric research ethics. Following the conference, a group of 12 experts met to review the state of research in the field.

They will produce an article later this year offering recommendations for best practices and further research. The conference was the first in a series of four.

- June 19: The Clinical Research Training Center held its 2<sup>nd</sup> annual Career Development Retreat. Approximately 80 individuals attended the retreat where speakers discussed leadership, teamwork, career advancement, and data management. Michael DeBaun, MD, MPH, Ferring Family Chair of Pediatrics and

Professor of Biostatistics and Neurology, opened with an excellent overview of successful team building. Roger Yussen, MD, MPH, Associate Professor of Medicine, followed with a practical discussion on academic career progression. Kenneth Schechtman, PhD, Associate Professor of Biostatistics, provided valuable information regarding data collection and management. We are indebted to our presenters, who were instrumental in making this year's retreat a success.

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## EVENTS & ANNOUNCEMENTS

### Major ICTS Events

- September 5: (8 AM–5 PM) *Community Engagement* hosts the Southeast Regional Conference at the Eric P. Newman Education Center.

- September 30: (5 PM CST) *KL2 Career Development Awards* deadline for applications. These awards are aimed at fellows, post-doctoral scholars, and junior faculty committed to multidisciplinary clinical and transla-

tional research. Information on how to apply may be found at <http://crscholars.im.wustl.edu/home-apply.php> or you may contact Alison Ebers at [aebers@im.wustl.edu](mailto:aebers@im.wustl.edu) or 314-454-8255.

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## IN THE NEWS:

- Graham Colditz, MD, MPH the Niess-Gain Professor, associate director of Prevention and Control at Siteman Cancer Center and ICTS Executive Committee member, was lead investigator on a study about girls and young women who exercise regularly between the ages of 12-35 and incidence of breast cancer before menopause. The May 21, 2008 volume of the Journal of National Cancer Institute contains an article pertaining to the study entitled "A Prospective Study of Age-Specific Physical Activity and Premenopausal Breast Cancer." J Natl Cancer Inst, 21 May 2008; 100: 728-737.

- The first publication acknowledging the NIH CTSA funding for the ICTS is:

Kauwe JS, Cruchaga C, Mayo K, Fenoglio C, Bertelsen S, Nowotny P, Galimberti D, Scarpini E, Morris JC, Fagan AM, Holtzman DM, Goate AM. "Variation in MAPT is associated with cerebrospinal fluid tau levels in the presence of amyloid beta deposition." Proc Natl Acad Sci USA. 2008 Jun 10; 105 (23):8050-4. Congratulations and thank you for appropriately acknowledging the funding sources. See the ICTS website for the [NIH Funding Acknowledgement](#) statement.

### Clinical Research Training Center

- 2008 Predoctoral Program: The CRTC Predoctoral Program began on Tuesday, June 3rd. The 33 students include 9 on the one-year intensive track and 24 on the summer research track. Of the 33 students, 19 are WU medical students, 3 are medical students from other institutions, 5 from the Program in Audiology and Communication Sciences, 1 from the Program in Occupational Therapy, and 5 from the St. Louis College of Pharmacy. Students take 2 courses in the summer: 1) Analysis of Clinical Data and 2) Designing Outcomes and Clinical Research and work in the clinical research lab with their mentor. The summer students will present their work at a symposium to be held in the Farrell Learning and Teaching Center on Tuesday, July 29.

## HAVE YOU MET? ANA S. ILTIS, PHD

Moving from Houston, Texas 6 years ago, Ana Iltis, PhD, Assistant Professor, has found a home in the Department of Health Care Ethics at Saint Louis University. As the Consultation Service Director and Course Director for Ethical and Regulatory Issues in Clinical Research, Dr. Iltis is the primary contact for the ICTS Center for Clinical Research Ethics (CCRE). The Graduate School at SLU, where Dr. Iltis is located, is an ICTS Partner Institution.

Addressing a common misconception, Dr. Iltis says, "Consulting with CCRE is just like discussing your biostatistics plan. We are not the ethics police. We help you determine the best study plan to avoid problems in the future."

Dr. Iltis' areas of expertise support the CCRE mission: 1) promoting research ethics education, 2) providing consultations and 3) conducting

research on research ethics. Her enthusiasm for the education component is evident as she describes how she enjoyed working with the WU Masters of Clinical Investigation (MSCI) students last semester. Consisting of a diverse group of students with unique study design issues including, disparate research populations. Dr. Iltis and guest instructors facilitated discussions to tease out appropriate study designs to avoid ethical or regulatory issues.

Her commitment to the second mission component is exemplified by her collaboration on a whitepaper about Research Ethics Consultation with representatives from other funded CTSA organizations. In addition, much of her time is spent on the third component, conducting her own research on research ethics.

What does she do with her spare time? For one thing, she, her husband and their 6 year old daughter love to travel. Their most recent trip was an auto tour of Alaska, complete with a brown bear encounter and a tour of the Denali National Park.

To learn more about the CCRE, contact Dr. Iltis at either [iltisas@slu.edu](mailto:iltisas@slu.edu), or [ccre@im.wustl.edu](mailto:ccre@im.wustl.edu) or 314-977-6661.



*Comments about ICTS  
News, suggested articles or  
questions should be directed  
to [ICTS@im.wustl.edu](mailto:ICTS@im.wustl.edu) or  
by contacting Jae Allen at  
314-362-9331.*